

Exhibit B



ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits

Special 510(k) Submission

November 23, 2009

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**Bard Peripheral Vascular, Inc.
C. R. Bard
1625 West Third Street
P.O. Box 1740
Tempe, AZ 85280-1740**

Indications for Use**510(k) Number (if known):****Device Name:** ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits**Indications for Use:**

The ECLIPSE™ Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- ECLIPSE™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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